Remarks

The Office Action mailed March 19, 2009 has been received and reviewed. Claims 1-52 are pending, of which claims 17-28 and 39-51 are withdrawn from consideration, leaving claims 1-16, 29-38, and 52 under consideration. Claims 2-4, 17-28, 36, and 39-51 are canceled without prejudice. Claims 53-63 are added. Claims 1, 12, 14, 29, 34, 35, 37, and 52 are amended. Thus, after entry of the amendments, claims 1, 5-16, 29-35, 37, 38, and 52-63 will be pending and under consideration. Reconsideration and withdrawal of the rejections are respectfully requested.

Interview Summary

Applicants thank Examiner Shafer and Examiner Spector for the courtesy of a telephone interview held July 21, 2009. Applicants' undersigned representative, Christopher Gram, participated on behalf of Applicants.

All of the claims and the Rosen document were discussed. No agreement was reached. However, Examiner Shafer and Examiner Spector provided helpful clarifications of the positions in the Office Action and guidance for responding to the outstanding rejections.

Claim Amendments

Claims 2-4, 17-28, 36, and 39-51 are canceled without prejudice.

Claim 1 is amended to recite that the isolated antibody is a monoclonal antibody. Support for the amendment may be found in Applicants specification at, for example, claim 2 as originally filed and paragraphs [0013], [0069], [0070], and [0072] (all references to locations in Applicants' specification refer to locations in U.S. Patent Application Publication No. US 2007/0258895 A1).

Claims 12 and 14 are amended to recite that the amino acid sequence administered to the animal comprises an amino acid sequence depicted at amino acids 13-27 of SEQ ID NO:1. Support for the amendment may be found in Applicants' specification at, for example, paragraph [0047].

Claim 37 is amended to change the claim from which it depends in light of the amendment to claim 29 and the cancellation of claim 36.

Claims 34 and 35 are amended to correct the identity of the claim from which each claim depends.

Claim 29 is amended to recite that analyzing the cell for a polypeptide comprises contacting the cell with an antibody that specifically binds to the amino acid sequence depicted at SEQ ID NO:1 or an immunogenic fragment thereof, and detecting the bound antibody. Support for the amendment may be found in Applicants' specification at, for example, paragraph [0092].

Claim 52 is amended to recite that the isolated antibody comprises a monoclonal antibody. Support for the amendment may be found in Applicants' specification at, for example, paragraphs [0072] and [0073].

New claims 53-60 are drawn to particular embodiments of an isolated monoclonal antibody that include an isolated humanized antibody and compositions that include such an antibody. Support for new claims 52-60 may be found in Applicants' specification at, for example, claim 4 as originally filed and paragraphs [0069], [0070], and [0073].

New claims 61 and 62 are drawn to particular embodiments of a method that employs a monoclonal antibody (claim 61) or a humanized monoclonal antibody (claim 62). Support for claims 61 and 62 may be found in Applicants' specification at, for example, paragraphs [0070] and [0073].

New claim 63 is drawn to a particular embodiment of a kit that includes a humanized monoclonal antibody. Support for claim 63 may be found in Applicants' specification at, for example, [0073].

Objection to Claims

Claims 30 and 34 are objected to as being duplicative claims. Claims 32 and 35 are similarly objected to as being duplicative claims. It appears that the objection to claims 30 and 34 should actually address claims 31 and 34. Applicants will treat the objection as such. If

Applicants are incorrect, clarification of the asserted duplication between claims 30 and 34 is respectfully requested.

Claims 34 and 35 are amended, obviating the objection. Applicants respectfully request that the objection to claims 34 and 35 as being duplicative of claims 31 and 32, respectively, be reconsidered and withdrawn.

The 35 U.S.C. §112, Second Paragraph, Rejection

Claims 29-38 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Office Action asserts that the claims omit essential steps. Claim 36 is canceled, obviating the rejection with respect to claim 36. Applicants respectfully traverse the rejection as it applies to claims 29-35, 37, and 38.

As discussed in Applicants' response filed January 12, 2009, Applicants respectfully submit that the claims do not omit essential steps. The Office Action asserts that the claims omit an active contacting step and a detection step. (Office Action, page 3). Applicants maintain that such steps are encompassed by the analyzing step as one of skill in the art would read and understand the analyzing step in light of Applicants' specification (see, e.g., paragraphs [0092] and [0093]).

Nevertheless, and solely to expedite prosecution, claim 29 is amended to recite a particular manner of analyzing the cell that expressly recites a step that involves detecting an indicator that the cell expresses the recited polypeptide.

Applicants respectfully submit that claims 29-35, 37, and 38 satisfy the requirements of 35 U.S.C. §112, second paragraph, and request that the rejection be reconsidered and withdrawn.

The 35 U.S.C. §102 Rejection

Claims 1-16, 29-38, and 52 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. 2007/0015271 (Rosen). Claims 2-4 and 36 are

canceled, obviating the rejection as it applies to those claims. Applicants respectfully traverse the rejection as it applies to claims 1, 5-16, 29-35, 37, 38, and 52.

Claims 1, 12, 14, 29, and 52 are independent. Each of claims 5-11 depends, directly or indirectly, from claim 1. Each of claims 13 and 15 depends, directly or indirectly, from claim 12. Claim 16 depends from claim 14. Each of claims 30-35, 37, and 38 depends, directly or indirectly, from claim 29. Each of the dependent claims includes all of the features recited in the claim or claims from which it depends. Consequently, remarks that refer, specifically or collectively, to one or more independent claims apply equally to any claim that depends from a referenced independent claim.

Claim 1 is drawn to an isolated monoclonal antibody that specifically binds to an amino acid sequence depicted at SEQ ID NO:1 or an immunogenic fragment thereof. Claim 12 is drawn a method of making an antibody that specifically binds to an amino acid sequence depicted at SEQ ID NO:1 or an immunogenic fragment thereof. Claim 52 is drawn to a kit that includes a monoclonal antibody or humanized antibody that specifically binds to an amino acid sequence of SEQ ID NO:1. Claim 29 is drawn to a method for detecting a polypeptide that is specifically recognized by an antibody that specifically binds to a polypeptide comprising the amino acid sequence of SEQ ID NO:1.

MPEP §2131 states, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Applicants respectfully submit that Rosen cannot anticipate claims 1, 12, 29, and 52 because Rosen fails to set forth each and every feature recited in claims 1, 12, 29, and 52.

The Office Action states that Rosen teaches "antibodies to the polypeptides taught in [Rosen], which include antibodies to the polypeptide of SEQ ID NO:5141[.]" (Office Action, page 5). SEQ ID NO:5141 is a 111 amino acid polypeptide that includes a six amino acid fragment–amino acids 90-95–that is 100% identical to amino acids 11-16 of SEQ ID NO:1 recited in claim 1. *Id.*

As Applicants' explained in the Office action filed January 12, 2009, Rosen teaches a polypeptide–SEQ ID NO:5141–and generally, albeit thoroughly, teaches the production of antibodies that can specifically bind a described polypeptide. However, Rosen fails to expressly describe an antibody that binds specifically to a polypeptide having the amino acid sequence of SEQ ID NO:5141. Moreover, Rosen fails to describe an antibody that specifically binds to amino acids 90-95 of SEQ ID NO:5141. Therefore, the validity of the rejection hinges on whether Rosen inherently teaches an antibody that binds to amino acids 90-95 of SEQ ID NO:5141.

M.P.E.P. §706.02(V) explains that "for anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present." (Emphasis added). Because Rosen fails to expressly describe an antibody that specifically binds to the polypeptide of SEQ ID NO:5141 and further fails to expressly describe an antibody that specifically binds to amino acid residues 90-95 of SEQ ID NO:5141, the rejection relies on Rosen inherently setting forth an antibody that specifically binds to amino acid residues 90-95 of SEQ ID NO:5141. Applicants respectfully submit that the Office Action fails to meet the required burden to establish that an antibody that specifically binds to amino acids 90-95 of SEQ ID NO:5141 is inherently set forth in Rosen.

The Federal Circuit and its predecessor court have both held that inherent anticipation occurs only when descriptive material that is not expressly described in a prior art document is necessarily disclosed–not merely possibly or even probably disclosed–in the prior art document. "Inherency … may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981). "Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295, 63 USPQ2d 1597, 1599 (Fed. Cir. 2002) (quoting *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)).

The descriptive material missing from Rosen includes description of an antibody that specifically binds a polypeptide that includes Applicants' SEQ ID NO:1 or an immunogenic fragment thereof. The Office Action asserts that amino acid residues 11-16 of Applicants' SEQ ID NO:1 are 100% identical to amino acid residues 90-95 of Rosen's SEQ ID NO:5141. Thus, the inquiry reduces to whether Rosen necessarily teaches generation of antibodies that specifically bind to amino acid residues 90-95 of Rosen's SEQ ID NO:5141. However, the teaching of Rosen fails to do so. If one skilled in the art were to attempt to generate antibodies against a polypeptide having the amino acid sequence of Rosen's SEQ ID NO:5141, the skilled person would not necessarily produce an antibody that specifically binds to amino acids 90-95 of SEQ ID NO:5141. Consequently, Rosen fails to set forth teaching that inherently discloses an antibody that specifically binds to Applicants' SEQ ID NO:1 or an immunogenic fragment thereof.

The Office Action deemed these remarks unpersuasive, stating:

> One of ordinary skill in the art would predict that injecting a polypeptide of 111 amino acids (SEQ ID NO:5141) or an antigenic fragment thereof would result in generation of a mix of antibodies, some of which would specifically bind to antigenic epitopes of two or more amino acid residues, including amino acid residues 90-95 of SEQ ID NO:5141; these residues are at the carboxy-terminal end, and would be recognized by the immune system of the animal.

(emphasis added).

Applicants respectfully submit that the rationale provided in the Office Action fails to establish that one skilled in the art, following the teaching of Rosen, would necessarily generate antibodies that specifically bind to amino acid residues 90-95 of SEQ ID NO:5141. M.P.E.P. §2112 reiterates the Federal Circuit in *In re Robertson*:

> To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'

Simply put, the Office Action offers no credible support for the position that the teaching of Rosen necessarily results in the production of any particular portion of Rosen's SEQ ID NO:5141. At most, Rosen teaches that the polypeptide of SEQ ID NO:5141 can result in the generation of a mixture of antibodies, some of which, as the Office Action asserts, may or may not bind to amino acids 90-95 of SEQ ID NO:5141, but would not necessarily bind to amino acids 90-95 of SEQ ID NO:5141.

The argument that one skilled in the art "would predict" the production of antibodies that bind to SEQ ID NO:5141 produces no more than "the possibility or probability" that the antibodies would specifically bind to any specific amino acid sequence of Rosen's SEQ ID NO:5141 such as, for example, amino acid residues 90-95.

Nevertheless, and solely to expedite prosecution, claims 1, 12, 14, 29, and 52 are amended.

Claim 1 is amended to recite that the antibody is a monoclonal antibody. Rosen does not teach the production of a monoclonal antibody that specifically binds to any amino acid sequence that corresponds to Applicants' SEQ ID NO:1.

Claims 12 and 14 are amended to recite that the amino acid sequence administered to the animal comprises an amino acid sequence depicted at amino acids 13-27 of SEQ ID NO:1. Rosen does not teach administering such an amino acid sequence to an animal.

With respect to claim 29, Applicants respectfully submit that Rosen fails to teach a method that includes analyzing a cell for a polypeptide that (a) has a molecular weight of 36 kDa as measured by SDS-PAGE, and (b) is recognized by an isolated antibody that specifically binds to a polypeptide comprising the amino acid sequence depicted in SEQ ID NO:1.

Claim 52 is amended to recite that the isolated antibody of the kit comprises a monoclonal antibody. Rosen does not teach the production of a monoclonal antibody that specifically binds to any amino acid sequence that corresponds to Applicants' SEQ ID NO:1.

Because Rosen neither expressly nor inherently sets forth each and every feature recited in Applicants' claims 1, 12, 14, 29, and 52, Rosen cannot anticipate those claims. Applicants

therefore respectfully submit that claims 1, 5-16, 29-35, 37, 38, and 52 are novel over Rosen and request that the rejection of claims 1, 5-16, 29-35, 37, 38, and 52 under 35 U.S.C. §102(e) as being anticipated by Rosen be reconsidered and withdrawn.

Summary

It is respectfully submitted that the pending claims 1, 5-16, 29-35, 37, 38, and 52-63 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted
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The undersigned hereby certifies that this paper is being transmitted via the U.S. Patent and Trademark Office electronic filing system in accordance with 37 CFR §1.6(a)(4) to the Patent and Trademark Office addressed to the Commissioner for Patents, Mail Stop **RCE**, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17th day of September, 2009.

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